PATENT
Customer No. 22,852
Attorney Docket No. 6832.0064

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
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Craig A. Rosen et al.	)	Group Art Unit: 1653
	)	
Application No.: 10/775,180	)	Examiner: Karen C. Carlson, Ph.D.
	)	
Filed: February 11, 2004	)	
	)	
For: ALBUMIN FUSION PROTEINS	)	Confirmation No.: 1800

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

SUPPLEMENTAL REPLY TO RESTRICTION REQUIREMENT

Applicants are in receipt of an Office communication dated March 1, 2006, which indicates that the reply to the Restriction Requirement filed by Applicants on December 15, 2005, is not fully responsive to the Restriction Requirement dated October 3, 2005, because Applicants have not elected a single sequence for search. The Office did not set a new period for response but instead, stated that the period for reply set forth in the prior Office Action has expired and therefore, Applicants must obtain extensions of time under 37 C.F.R. § 1.136(a).

First, Applicants respectfully object to the Office's failure to give Applicants a new statutory period for response because Applicants assert that their reply dated December 15, 2005, was a bona fide response. Although the Restriction Requirement dated October 3, 2005, stated that "Inventions 1-161 [corresponding to Fusion Nos. 1-161 in

Table 2] are patentably distinct one from the other," the Restriction Requirement did not clearly state that an election of a single sequence was required. Instead, the claims were grouped into 7 different groups as follows:

> 1-161, claims 1-13, drawn to albumin fusion proteins NO:1 to NO:161, from Table 2, Class 530/350;
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> 162-322, claim 14, drawn to method of treating disease via administration of albumin fusion proteins NO:1 to NO:161 from Table 2, Class 514/2;
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> 323-483, claim 15, drawn to method of treating metabolic disorders via administration of albumin fusion proteins NO:1 to NO:161 from Table 2, Class 514/2;
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> 484-644, claims 16-25 and 27, drawn to method of treating diabetes via administration of albumin fusion proteins NO:1 to NO:161 from Table 2, Class 514/2;
>
> 645-805, claims 26 and 28, drawn to method of treating obesity via administration of albumin fusion proteins NO:1 to NO:161 from Table 2, Class 514/2;
>
> 806-966, claim 29, drawn to method of extending the shelf life of albumin fusion proteins NO:1 to NO:161 from Table 2, Class 514/2; and
>
> 967-1127, claims 30-32, drawn to nucleic acid encoding albumin fusion proteins NO:1 to NO:161 from Table 2, Class 536/23.1.

In the Amendment and Reply to Restriction Requirement filed December 15, 2005, Applicants traversed the requirement for restriction but also " provisionally elect[ed] to prosecute Group V, drawn to a method of treating obesity," encompassing claims 26 and 28. Because the Restriction Requirement did not clearly state that a single sequence was required, Applicants believe that they had fully complied with the Restriction Requirement. Accordingly, Applicants believe that it would have been reasonable to give Applicants a new period for response to address the Office

communication dated March 1, 2006, and that no extensions of time are required. *See* 37 C.F.R. § 1.135(c).

Nonetheless, as elected in the prior response, Applicants provisionally elect with traverse, within Group V, encompassing claims 26 and 28, which are drawn to a method of treating obesity via administration of albumin fusion proteins. In the Office communication dated March 1, 2006, the Office also appears to require a species election of a single sequence for search. In the interest of furthering prosecution, but in no way acquiescing to the restriction and species requirements, Applicants provisionally elect, with traverse, the amino acid sequence comprising amino acids 30-674 of SEQ ID NO:447, which corresponds to the albumin fusion protein encoded by Fusion No. 137 in Table 2, for search purposes. Applicants also request the Office to grant any extensions of time required to enter this response and authorize the Office to charge the required fees to our deposit account 06-0916.

The originally-filed claims subject to the Restriction Requirement encompassed albumin fusion proteins comprising an albumin or fragment or variant of albumin and a Therapeutic protein X, which is selected from the therapeutic proteins listed in Table 1. In traversing the Restriction Requirement, Applicants pointed out in their December 15, 2005, response, that all of the albumin fusion proteins listed in Table 2 are simply specific examples of albumin (or fragment or variant thereof) fused to Therapeutic protein X listed in Table 1. Specifically, page 21, paragraph [0069] of the specification explains that Table 1 provides a list of therapeutic proteins that correspond to a therapeutic protein portion of an albumin fusion protein of the invention. The text at page 22, lines 4-7 of the specification explains that column "Construct ID" in Table 1

"provides a link to an ***exemplary*** albumin fusion construct disclosed in Table 2 which encodes an albumin fusion protein comprising the referenced Therapeutic Protein X portion" (emphasis added). Applicants need not be limited to the inventions where specific examples are disclosed. *See* MPEP 2164.02. Therefore, Applicants reassert that the species requirement based on the specific constructs listed in Table 2 is improper.

Moreover, when Table 1 lists constructs for a specific Therapeutic protein X under column "Construct ID," all of those constructs encode an albumin fusion protein comprising that Therapeutic protein X. For example, GLP-1 is listed in Table 1 (page 23) under column "Therapeutic Protein:X," and column "Construct ID" includes, among other constructs, Construct ID No: 3070, which corresponds to Fusion No. 137 in Table 2. However, all of the other constructs listed in that same column "Construct ID" also encode an albumin fusion protein comprising a GLP-1 polypeptide. Therefore, Applicants respectfully submit that it would not have posed a serious burden on the Examiner to search for an albumin fusion protein comprising a GLP-1 polypeptide as a single group. More specifically, it would not have posed a serious burden on the Examiner to search for the "[m]ethod of treating obesity or of losing weight in a patient, comprising administering an albumin fusion protein comprising two or more tandemly oriented GLP-1 polypeptides . . ." as recited in previously presented claim 26 and claims 33-77 (all dependent on claim 26) (*see e.g.*, claim 26 filed in the Amendment and Reply to Restriction Requirement filed December 15, 2005). Applicants note that the elected method of treating obesity by administration of the provisionally elected amino acid sequence comprising amino acids 30-674 of SEQ ID NO:447, which corresponds to the

albumin fusion protein encoded by Fusion No. 137 (Construct ID No. 3070) in Table 2, is specifically covered by claim 69(h).

In view of the foregoing and of the arguments already made in the prior response filed December 15, 2005, Applicants respectfully request that the Office reconsider and withdraw the Restriction Requirement of October 3, 2005. Applicants previously extended the period for reply to January 3, 2006, with a request for an extension of two months and payment of the required fees filed concurrently with the bona fide response of December 15, 2005. Applicants believe that they should have received a new period for response to the Office communication dated March 1, 2006, as discussed above, and that no extension of time is required because this response is being timely filed within one month of that Office communication. However, should the Office maintain the initial period of response, Applicants request the Office to grant any extensions of time required to enter this response and authorize the Office to charge all required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: March 31, 2006

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